



Welcome to this edition of *Hospital Happenings*, a newsletter published by the North Dakota Department of Health, Division of Health Facilities. *Hospital Happenings* is designed to help hospitals stay up-to-date on various issues. Please share with your staff.

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YES, YOU CAN USE SIDE RAILS. BUT . . .

By Joyce Johnson, Joan Coleman and Bridget Weidner

Many health-care facilities continue to use side rails for various reasons, but side rails pose a significant risk to patients. Risks include entrapment and the potential for increased injury when a fall occurs from a bed with elevated side rails. Care must be taken to ensure patient safety.

Many factors need to be considered before making the decision to use side rails. The Centers for Medicare and Medicaid Services (CMS) does consider the use of side rails to prevent a patient from voluntarily getting out of bed as a restraint. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment.

The regulations at 42 CFR 482.13 (e) state that all patients have the right to be free from restraints. A restraint may be imposed to ensure the immediate safety of the patient, a staff member or others and must be discontinued at the earliest possible time.

The process starts with a comprehensive individualized patient assessment. This assessment is used to determine whether the use of less restrictive measures poses a greater risk than the use of a restraint. The patient's medical condition or symptoms must warrant the use of side rails as a restraint. The need must be reassessed on a regular basis and with any change in condition.

Attempts should be made to use the least restrictive device necessary to meet the patient's needs. The use of a restraint must be in accordance with a written modification to the patient's plan of care and be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient and authorized to order restraints. These orders must never be written as a standing order or on an as-needed basis. The attending physician must be consulted as soon as possible if the attending physician did not order the restraint. Staff must be trained on the safe use of restraints.

The death reporting requirements at 42 CFR 482.13 (g) require hospitals to report all deaths associated with the use of a restraint, including side rails when used as a restraint, to CMS. This reporting requirement does not apply to CAHs however this rule does apply to CAH District Part Units. The Region VIII contact is Helen Jewell at 303.844.7048.

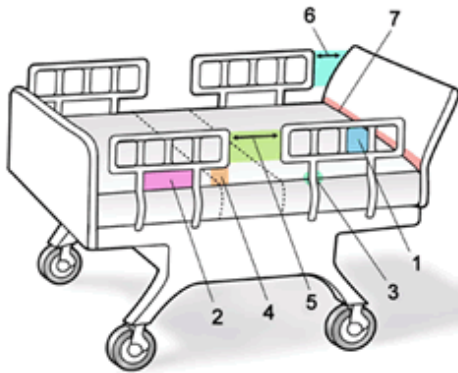
In the past 21 years, the U.S. Food and Drug Administration (FDA) received 691 entrapment reports, 413 of which resulted in death. Entrapment is most likely to occur with a frail, elderly patient. Patients may attempt to exit the bed due to confusion, pain, hunger, thirst, and/or the need for repositioning or toileting. The FDA has identified zones that present a risk for entrapment. The FDA provides dimensional recommendations for zones 1 through 4, since 80 percent of entrapment cases have occurred in these areas.

(Continued on page 2)



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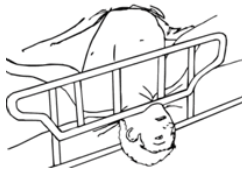
(Continued from page 1) Yes, You Can Use Side Rails. But . . .



Zone 1: Within the rail — any open space between the perimeters of the rail can present a risk for head entrapment. Recommended space: less than 4 3/4 inches.



Zone 2: Under the rail, between rail supports, or next to a single rail support — the gap under the rail between the mattress and the bottom edge of the rail may allow for head entrapment.



Recommended space: less than 4 3/4 inches.

Zone 3: Between the rail and the mattress — if too large it can create a risk for head entrapment. Recommended space: less than 4 3/4 inches.



Zone 4: Under the rail at the ends of the bed — a gap between the mattress and the lower portion of the rail poses a risk of neck entrapment. Recommended space: less than 2 3/8 inches.



Zone 5: Between split rails — when partial or split rails are used on the same side of the bed, the space between the rails may present a risk for neck or chest entrapment.



Zone 6: Between the end of the rail and the side edge of the headboard or footboard — a gap between the end of the rail and the side edge of the headboard or footboard can present the risk of patient entrapment.



Zone 7: Between the headboard or footboard and the end of the mattress — when there is too large a space between the inside surface of the headboard or footboard and the end of the mattress, risk of head entrapment increases.



Creating a safe patient environment does not necessarily rule out the use of side rails. The decision to use side rails should be based on assessment and identification of the patient's needs and include a risk versus benefit analysis. Detailed information regarding entrapment, patient assessment, care planning, and assessing facility beds may be found at www.fda.gov/cdrh/beds/guidance/1537.html.

References:

State Operations Manual Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

U.S. Food and Drug Administration Website for Medical Device Safety: www.fda.gov/cdrh/beds/guidance/1537.html.

Direct Supply, Beds & Entrapment: What You Need to Know to Reduce Your Risk

CDC RESOURCE

The U.S. Centers for Disease Control and Prevention has created a new webpage that provides all-hazards resources intended for individuals at health-care facilities tasked with ensuring that their facility is as prepared as possible for an emergency. The health-care facilities targeted by this page include hospitals, long-term acute and chronic-care facilities, outpatient clinics and urgent-care facilities, physicians' offices, and pediatric offices and hospitals.

See <http://emergency.cdc.gov/healthcare>.



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NEW SURVEY AND CERTIFICATION LETTERS

The Centers for Medicare and Medicaid Services (CMS) transmits memoranda, guidance, clarifications and instructions to state survey agencies and CMS regional offices through use of survey and certification (S&C) letters. Below is a list of the new S&C letters affecting hospitals since Nov. 21, 2008.

The S&C letters are available at

www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage.

- S&C 09-15 New CAH Requirements Under 42 CFR 485.610 (e) Related to CAH Co-location and Provider-based Locations.

CMS published a final rule in the Nov. 27, 2007, Federal Register (72 Fed. Reg. 66934) amending 42 CFR Part 485 Subpart F, adding a new standard at 485.610 (e) governing a CAH's location relative to other hospitals or CAHs with respect to co-location and off-campus provider-based arrangements. These amendments became effective Jan. 1, 2008.

- S&C 09-21 2009 Physician Fee Schedule Changes Affecting the Survey & Certification of Rehabilitation Programs.

On Nov. 9, 2008, CMS published revisions and updates to payment policies, as well as conditions of participation (CoPs) under the Physician Fee Schedule. These changes affected several CoPs and conditions for coverage listed in this memo.

- S&C 09-25 Enforcement of Amended Requirements for Certain Hospital and CAH Disclosures to Patients.
 1. Revision to Physician-owned Hospital Disclosure Requirements. 42 CFR 489.3 and 489.20 (u) and (v) were amended, effective Oct. 1, 2008, to: Expand the definition of physician-owned hospital to include a participating hospital in which a physician or immediate family member of a physician has ownership interest in the hospital; Require hospitals/CAHs to provide a list of physician owners at the time a patient requests it; Require hospitals/CAHs to make disclosure at the time of referral a condition of medical staff membership for referring physician owners; and Exempt from the disclosure requirements hospitals whose physician owners do not refer patients.
 2. Clarification of Termination Basis. 42 CFR 489.53 was also amended as of Oct. 1, 2008, to clarify that CMS may terminate the provider agreement of hospitals or CAHs that fail to make required disclosures, including disclosures when a hospital does not have a physician on site 24/7.

NOTICE OF INTENT TO AMEND ADMINISTRATIVE RULES

The North Dakota Department of Health held a public hearing Feb. 26, 2009, to address a proposed amendment to North Dakota Administrative Code Section 33-07-01.1-20, Medical Records Services. Written or oral comments on the proposed amendment received by the Department of Health by March 13, 2009, will be fully considered. The underlined text is to be added to the following section:

33-07-01.1-20 (1)(i)(2)

(2) Telephone and verbal orders may be used provided they are given only to qualified licensed personnel and reduced to writing and signed or initialed by a licensed health care practitioner responsible for the care of the patient on or before the patient's next visit or within thirty days, whichever comes first.



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SMOKING MATERIALS AT DESIGNATED SMOKING AREAS

By Monte Engel, Manager
Building Standards and Life Safety Code

The Life Safety Code requires that ashtrays of noncombustible material and safe design and metal containers with self-closing cover devices into which ashtrays can be emptied be available in all areas where smoking is permitted. This applies to both indoor and outdoor designated smoking areas.

Our office has continued to receive questions about the use of the smoking “outposts”. These are the barrel shaped, noncombustible containers with the tall tapered neck into which cigarettes can be disposed.

Prior directions to our office had always indicated these products were not acceptable for use in meeting the requirements of the Life Safety Code at designated smoking areas. However, the Centers for Medicare and Medicaid Services Regional Office recently indicated the “outposts” are approved and can be used to meet the Life Safety Code requirements for ashtrays and the containers into which the ashtrays are emptied.

Therefore, we will accept the use of the smoking “outposts” at designated outdoor smoking areas.



*One must have a mind of winter
To regard the frost and boughs
Of the pine-trees crusted with snow;
And have been cold a long time
To behold the junipers shagged with ice,
The spruces rough in the distant glitter*

*Of the January sun; and not to think
Of any misery in the sound of the wind,
In the sound of a few leaves.*

~ Wallace Stevens, *The Snow Man*, 1923

POSTING OF KEYPAD CODES

By Monte Engel, Manager
Building Standards and Life Safety Code

A request for Life Safety Code interpretation was recently forwarded to the Centers for Medicare and Medicaid Services (CMS). This question had to do with whether locked doors equipped with keypads were required to have the code posted at the door. This code when entered in the keypad would unlock the door.

The response from CMS indicated the Life Safety Code **does not** require that a provider post the security code for keypads of locked doors next to or nearby any keypad.

However, it is CMS's expectation, that during a Life Safety Code survey, K038 will be cited if egress doors on a floor are locked and there is evidence that all cognitively aware residents/patients, staff and visitors do not have access to the method of opening the doors.

If staff is not aware of how to open the egress doors or cannot open the egress doors, it is very likely an **IMMEDIATE JEOPARDY** situation.

Please note that this information is applicable only to keypads and the posting of the bypass code. If doors are equipped with locking hardware where pushing on the door for a period of time results in the unlocking of the door, then a sign instructing this procedure must be posted. Refer to Section 7.2.1.6.1 of the 2000 Life Safety Code for further information about this sign.



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